IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
Fort Worth Division

OUTSOURCING FACILITIES ASSOCIATION, et al., Plaintiffs, v. UNITED STATES FOOD AND DRUG ADMINISTRATION, et al., Defendants.	Civil Action No. 4:24-cv-00953-P

Plaintiffs' Memorandum of Law in Support of
Motion for Injunction Pending Appeal

On March 25, 2025, this Court denied the parties' joint request that it convert its preliminary-injunction order into a final judgment. ECF No. 116. The Court has indicated that it will retain this action for at least another month to adjudicate cross motions for summary judgment. The order perpetuates the irreparable harm this Court already found to exist. To obtain timely relief, Plaintiffs seek an injunction pending appeal to preserve the status quo while the appeal proceeds and while this Court considers further arguments on the merits. This Court has jurisdiction to issue an injunction to preserve the status quo, notwithstanding the pending appeal. *See Coastal Corp. v. Texas E. Corp.*, 869 F.2d 817, 819–20 (5th Cir. 1989).

The arguments in support of this motion do not differ materially from those the Court addressed in its preliminary-injunction order. If the Court is not inclined to reconsider its order, it should promptly deny this motion so that Plaintiffs may renew it in the Fifth Circuit. In all events, Plaintiffs request a ruling by April 2, 2025.

ARGUMENT

"To obtain an injunction pending appeal," a movant "must show (1) a strong likelihood of success on the merits; (2) irreparable injury in the absence of an injunction; (3) that the balance of hardships weighs in their favor if injunctive relief is granted; and (4) that the public interest favors such relief." *Whole Woman's Health v. Jackson*, 13 F.4th 434, 441 (5th Cir. 2021). These elements are met here.

A. Plaintiffs Are Likely to Succeed on the Merits

Plaintiffs have multiple avenues to success on the merits, and they have a strong likelihood of prevailing.

1. FDA erroneously issued the Delisting Action without notice-and-comment rulemaking. The Delisting Action is a substantive rule subject to the APA's notice-and-comment mandate because it "create[s] law" by "affecting rights and obligations." *Shell Offshore Inc. v. Babbitt*, 238 F.3d 622, 628 (5th Cir. 2001). The Delisting Action creates law by prohibiting all compounding of tirzepatide by Section 503B outsourcing facilities and compounding drugs that are essentially copies of branded tirzepatide products by Section 503A pharmacies. *See* ECF No.

101 at 3. The default notice-and-comment requirement therefore applies to delisting actions unless another statute "*expressly*" modifies that requirement. 5 U.S.C. § 559 (emphasis added). The Court has recognized that the FDCA "is seemingly silent as to what procedure the FDA must use to make its shortage determinations." ECF No. 101 at 7. That silence is the very opposite of an express exemption from the notice-and-comment requirement. The Court, at most, identified tension between the shortage scheme and notice-and-comment rulemaking, ECF No. 101 at 10–11, but that is far short of an express exemption, *Mann Construction, Inc. v. United States*, 27 F.4th 1138, 1145–48 (6th Cir. 2022), and the Court did not consider that the APA's notice-and-comment provisions permit an agency to act quickly and with confidentiality. ECF No. 98 at 3.

The Delisting Action is not the product of an informal adjudication. The Delisting Action "bear[s] all the hallmarks…of rulemaking, not adjudication." *City of Arlington, Tex. v. F.C.C.,* 668 F.3d 229, 242 (5th Cir. 2012). Issuance of a generally applicable legal prohibition "is classic rulemaking" and not the proper subject of an adjudication. *Id.* at 243. The Court's order emphasizes the discretion an agency has to choose to engage in rulemaking or adjudication. ECF No. 101 at 8–11. But "when an agency chooses to issue a rule, … it must follow the procedures indicated in § 553." *Safari Club Int'l v. Zinke*, 878 F.3d 316, 332 (D.C. Cir. 2017). "An agency may not escape the requirements of § 553 by labeling its rule an 'adjudication.'" *Id.* The Delisting Action is "generally applicable" with "future impact" and thus is a rule. *Id.* at 332–33. Moreover, there was *no* adjudication: *none* of the pharmacies and facilities whose rights were the object of this so-called "adjudication" were party to it. Lilly was also not a party to this "adjudication," and the Delisting Action does not identify it as one. Indeed, it was *undisputed* that there were no parties to this supposed "adjudication." Yet the Court did not address Plaintiffs' central argument that there was no adjudication at all.

The Court's order misreads governing precedent by finding that the Delisting Action is not a rule because it "has immediate legal consequences for specific parties." ECF No. 101 at 15. The language the Court used, taken from *Safari Club*, differentiates "retroactive" determinations from prospective determinations. *See* 878 F.3d at 333–34 ("It was not retroactive because their issuance

resulted in no immediate legal consequences for any specific parties."). Here, the Delisting Action is not retroactive: unlike an enforcement action, it does not result in the punishment of compounders for action taken while tirzepatide was in shortage. The fact that the Delisting Action "has immediate legal consequences" on a *prospective* basis is precisely why it is a rule. ECF No. 101 at 15. The Court also proposed that this case is "unlike *Safari Club*, where the [agency's] findings 'implemented and interpreted a rule's enhancement requirement' to make a policy judgment about what level of protection elements needed to be afforded to enhance their survival." *Id.* But there is no distinction. Just as the agency in *Safari Club* implemented and interpreted a rule in making a factual finding that sport hunting of African elephants in Zimbabwe would not enhance the survival of the species, and thus "suspended the importation of sport-hunted elephant trophies" prospectively, 878 F.3d at 323–24, FDA implemented and interpreted the governing statutes to find that tirzepatide is not in shortage, and thus suspended compounding prospectively. The Court also analogized the Delisting Action to FDA's approval of a new drug application (NDA). ECF No. 101 at 13. But FDA's consideration of an NDA is an adjudication of the rights of a party (the applicant) before the agency that, in turn, has collateral legal consequences on third parties. *See Safari Club*, 878 F.3d at 334 (discussing adjudication of applications). That is entirely different from an agency's simply declaring generally applicable legal consequences, as FDA did here.

Finally, there is no "'lose-lose scenario' for Plaintiffs" in these claims. ECF No. 101 at 11. The Court was mistaken in its belief that Plaintiffs' arguments mean "the FDA's listing of the Lilly Drugs without notice and comment … is invalid and Plaintiffs should not have been allowed to compound their versions of the drugs." *Id.* For one thing, the APA directs that the process "required" to promulgate a rule be used to rescind it, not that whatever the agency did at the outset necessarily applies to amendments or repeal. *Perez v. Mortgage Bankers Ass'n*, 575 U.S. 92, 101 (2015). Two wrongs do not make an APA right. Moreover, the Delisting Action can stand only on the basis FDA supplied in the action itself. *Dep't of Homeland Sec. v. Regents of the Univ. of California*, 591 U.S. 1, 20 (2020). FDA did not state in the Delisting Action that a basis was invalidity of the original listing action. *Cf. id.* at 26 (agency action issued because government

concluded it "is illegal"). If FDA had reached such a view, it would nonetheless be required to evaluate obvious alternatives to simple rescissions, such as whether the original action could be justified under the "good cause" exception to notice-and-comment rulemaking, 5 U.S.C. § 533(d)(3), or reissued under different procedures, *see Regents of the Univ. of California*, 591 U.S. at 27 (finding that agency acted arbitrarily and capriciously, even though it properly found prior policy unlawful, because it failed to consider partial rescission rather than total rescission).

2. FDA violated the APA separately by resolving the shortage without a sufficient factual basis, coherent findings, or a proper implementation of the statutory directive. The very data on which the agency relied in making its decision [redacted] At the same time, the agency (and the Court) dismissed evidence from the same time period and thereafter—right up to the time of decision—that major national wholesalers had limited or no supply of brand-name tirzepatide products and reported, in some instances, that availability would be impaired for many months. *Id.* at 6–7.

FDA was obligated to find supply and demand based on an up-to-date time period. But FDA did not select a time period; [redacted] The Court's order was unfair in accusing Plaintiffs of having "assert[ed] that the FDA

failed to identify a specific time frame and in another [breath] that the FDA's time frame was erroneous." ECF No. 101 at 18. The fact that Plaintiffs could tell Lilly's presentations were inconsistent in time period—[redacted]—confirms that the agency did not select a time period for analysis. Indeed, FDA argued, not that it had deliberately chosen a time period for analysis, but that "the statute requires no" "precise window of time" at all. ECF No. 83 at 12.

The Court's order treats FDA as having analyzed [redacted] and that even Lilly did not argue the shortage was resolved until August 2024. Moreover, the use of cumulative figures [redacted] prevented FDA's analysis from being "up to date." *Compare id.* at 10–11 (describing what up-to-date determination might look like) *with id.* at 18–19 (excusing FDA from anything like that type of determination). The Court's order acknowledged that "there were data points from shorter periods of time, within the overall time frame, that could lead to a different result," ECF No. 101 at 22, but missed that data of that type was not merely "shorter time periods," but [redacted]. ECF No. 65 at 16; ECF No. 98 at 5.

The Court excused FDA from any requirement of rationality in finding that [redacted] on the ground "that a period of time requires a starting and ending point." ECF No. 100 at 23. That only begs—and does not answer—the question of [redacted] Both the statute and the Delisting Action treat the question of "demand" and "projected demand" separately. 21 U.S.C. § 356c(h)(2). [redacted]

For similar reasons, the Court's discussion of one alternative basis of review, "a month-to-month" review, ECF No. 100 at 22, is problematic. A month-to-month review is far closer to the statutory requirement that determinations be up-to-date [redacted]

[redacted]

And the Court's belief that FDA could make such a glaring error and yet justify harming a vast number of patients, ECF No. 100 at 24, is untenable. *Louisiana v. United States Dep't of Energy*, 90 F.4th 461, 470 (5th Cir. 2024) (arbitrary-and-capricious review is not "toothless").

The trove of evidence showing that pharmacies cannot order tirzepatide products from wholesalers confirms a shortage. FDA000607–1606. It is not correct to construe the record to support FDA's belief that this evidence reflects localized shortages inevitably resolved in "a day or two." ECF No. 101 at 25. The record shows pervasive, nationwide delays that are substantial. Among other things, the record includes more than 100 pages of screen shots showing that pharmacies had limited or no supply of brand-name tirzepatide products. *See* FDA679–693; FDA710–713; FDA849–853; FDA857–60; FDA982–1017; FDA1521–1584; FDA1590–1606. These include statements by wholesalers that Lilly did not provide a date by which there was an expected availability of product in its distribution center and that the estimated time of arrival was June 2025.

B. The Equitable Factors Favor an Injunction

The equities are clear-cut in favor of an injunction pending appeal, which would afford substantial benefit for no cognizable harm. Here, patient needs have been satisfied for two years by compounding, as Congress contemplated. To permit compounding for the short duration of an appeal will secure access to needed medication and avoid irreparable harm.

The Court correctly found that, without a temporary injunction, Plaintiffs will suffer "irreparable harm," ECF No. 101 at 29, and that harm ongoing each day this case progresses without an injunction. The balance of harms and public interest also favor an injunction. the public has a substantial interest in continued access to compounded tirzepatide. Tirzepatide treats serious conditions, and patient need has been supplied for two years in meaningful part through compounding. The "access to…medical treatments is unquestionably in the public interest." *Dumanian v. Schwartz*, 2022 WL 2714994, at *15 (N.D. Ill. July 13, 2022); *see also Med-Cert Home Care, LLC v. Azar*, 365

F.Supp.3d 742, 758 (N.D. Tex. 2019) (granting injunctive relief because of the public's strong interest in access to health care); *Benson v. St. Joseph Reg'l Health Ctr.*, 2005 WL 6459109, at *2 (S.D. Tex. Dec. 22, 2005) (noting "the important public interest in open and fair competition for health services"); *Bos. Heart Diagnostics Corp. v. Health Diagnostics Lab'y, Inc.*, 2014 WL 2048436, at *2 (D. Mass. May 16, 2014) (recognizing the "public's interest in having access to medical treatment"). Without an injunction, FDA's unlawful action will deprive an untold number of patients of access to provider-prescribed treatment. Moreover, the public also has a "substantial public interest in having governmental agencies abide by the federal laws that govern their existence and operations." *Texas v. United States*, 40 F.4th 205, 229 (5th Cir. 2022). It is "not in the public interest to suspend notice and comment," which "are basic to our system of administrative law." *Nat. Res. Def. Council v. Nat'l Highway Traffic Safety Admin.*, 894 F.3d 95, 115 (2d Cir. 2018).

No cognizable harms weigh on the other side of the scale. FDA cannot plausibly claim injury from following congressional dictates and making a reasonably informed—rather than arbitrary—decision or from a continuation of the state of affairs that begun in December 2022. Nor can FDA credibly allege a public-safety risk, especially given its extension of enforcement discretion to authorize compounding for months following the Delisting Action. Lilly also cannot claim cognizable harm. By Lilly's own account, it is not losing out on sales. According to Lilly, [redacted] Decision 14. Any cost to Lilly would be de minimis in light of its $45 billion annual revenues.

CONCLUSION

The Court should grant the motion and issue an injunction pending appeal. Alternatively, if the Court is not so inclined, it should deny the motion promptly and without response to permit Plaintiffs to renew the request in the Fifth Circuit.

Dated: March 26, 2025

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